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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/956,518 10/23/97 LEONARD S UTC-03042

HM12/0609

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EXAMINER

HAYES, R

ART UNIT	PAPER NUMBER
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1645

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DATE MAILED:

06/09/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/956,518

Applicant(s)
Leonard et al

Examiner
Robert C. Hayes

Group Art Unit
1645



- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-25 is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-25 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1, 3-8, drawn to nucleic acid molecules encoding the alpha-7 nicotinic receptor, vectors and host cells, classified in class 435, subclass 325.
 - II. Claim 2, drawn to alpha-7 nicotinic receptor polypeptides, classified in class 530, subclass 350.
 - III. Claims 9-13, drawn to a method of detecting alpha-7 nicotinic receptor polynucleotides in a biological sample, classified in class 435, subclass 5.
 - IV. Claim 14-25, drawn to method of amplifying alpha-7 nicotinic receptor polynucleotides, classified in class 435, subclass 91.2.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different products; restriction is deemed proper because these products appear to constitute patently distinct inventions for the following reason:

Groups I-II are directed to products that are physically and functionally distinct that involve nucleic acids or proteins. Each of these products can be prepared by different processes, such as though chemical synthesis or isolation from natural sources using various isolation/

Art Unit: 1645

purification procedures. For example, the polypeptides of Group II are fundamentally different molecules than the polynucleotides of Group I, which in turn can be used to clone proteins, detect expression of the gene product, or used as therapeutic agents in gene therapy. Alternatively, the proteins of Group II can be utilized to generate antibodies. It is pointed out that there is a proper distinction between these groups, since each product is not required in order for the other to exist. Thereby, these groups are distinct and separable for the reasons stated.

Groups I and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the nucleic acids can be used in materially different processes, such as to encode the full length protein or used in gene therapy. The method of detecting and amplifying nucleic acid molecules requires primers and appropriate salt and hybridization conditions, which are not required for the products of Group I. It is further noted that the methods of Groups III & IV do not require the products of Group II.

Although there are no provisions under the section for "Relation of Inventions" in MPEP 806.05 for inventive groups that are directed to different methods; restriction is deemed proper because these methods appear to constitute patently distinct inventions for the following reason:

Art Unit: 1645

Groups III-IV are directed to methods of detecting or amplifying nucleic acid molecules. Each of the methods require physically and functionally distinct elements. For example, the method for detecting the presence of a nucleic acid molecule is distinguished from the method for amplifying a nucleic acid by PCR of Group IV, in that the diagnostic method of Group III requires inclusion of labeled nucleotides, unlike the PCR method of Group IV, which requires appropriate primers. Moreover, the method involving generation of PCR reaction products require purification protocols specific to isolating and detecting small nucleic acid molecules, unlike the method of Group III. These inventions are, therefore, patentably distinct, since one is not required for the other.

3. Because these inventions are distinct for the reasons given above, they have acquired a separate status in the art as shown by their different classification, and the non-coextensiveness of the search and examination for each group would constitute an undue burden on the examiner to search and consider all the separable groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

Art Unit: 1645

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

4. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Robert C. Hayes, Ph.D.
June 8, 1999



ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600